K020504

EXHIBIT#1

FEB 2 8 2002

Special 510(K) SUMMARY

This summary of Special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

1. Submitter's Identification:

Radiant Innovation Inc.,
No. 40, Lane 19, Bade Road
Hsin-Chu City
Taiwan, R.O.C.

Contact:

Mr. Charles Chang
Eng. Dep. Manager

Date Summary Prepared: Feb/07/2002

2. Name of the Modification Device:

Infrared Ear Thermometer, Models TH88 series

3. Current Clearance Device:

Radiant Innovation Infrared Ear Thermometer, Models TH8 series.(FDA# K011059)

4. Device Description:

The Radiant Innovation Inc., Infrared Ear Thermometer, Models TH88 series are electronic thermometers using an infrared detector (thermopile detector) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces of the patient.

To measure ear temperature, the ear thermometer is inserted into a patient's outer ear canal. A start button is pressed to start the measurement through the radiation exchanges. The electrical signal read out from the detector is fed to the circuit for amplification and calculation. The measured temperature then appears on a LCD display. The total operation takes a few seconds.

300 新竹市八德路19巷40號 No. 40, Lane 19, Pa-Der Road, TEL : 886-3-562-87

5. **Intended Use:**

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. **Comparison to the Cleared Devices:**

The RII Infrared Ear Thermometer, Models TH88 series are substantially equivalent to RII's current clearance device: Infrared Ear Thermometer, Models TH8 series, on the principle of operation, scientific technology with the same intended use, technological characteristics and specifications.

The only differences between TH8 and TH88 series Infrared Ear Thermometer are the outer appearance and addition operation procedures for probe cover installation on the user's manual which will not significantly change the safety and effectiveness .

7. **Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965, as well as IEC 60601 -1 and IEC 60601-1-2 requirements.

Guidance Documents included the FDA "*Guidance On The Content of Premarket Notification (51 0(k)) Submissions for Clinical Electronic Thermometers*", " *How to Prepare A Special 510(k)* ", "*Deciding When to Submit a 510(k) for a Change to an Existing Device*"..

9. **Conclusions:**

The RII Infrared Ear Thermometer, Models TH88 series, have the same intended use and similar characteristics as the cleared device, Model TH8 series. Moreover, bench testing contained in this submission supplied demonstrate that the modification of TH88 do not raise any new questions of safety or effectiveness. Thus, the RII Infrared Ear Thermometer, Models TH88 series is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Radiant Innovation, Incorporated
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K020504
Trade/Device Name: Infrared Ear Thermometer, Models TH88 Series
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 13, 2002
Received: February 15, 2002

Dear Ms. Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

#EXHIBIT B

Indications for Use Statement

Special 510(k) Number (if known):

Device Name: Radiant Innovation Inc. Infrared Ear Thermometer, Models TH88 series

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020504

PrescriptionUse_____ **OR** **Over-The-Counter Use ✓**
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**